

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

FILED
UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO

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Plaintiff,

Robert J. Scallen
CLERK ALB. CLERIQUE

vs.

Cause No. CIV 99-577 JC/WWD

GALEN D. KNIGHT, an individual;
and TERENCE J. SCALLEN, an individual;

Defendants.

**DEFENDANTS' KNIGHT AND SCALLEN AMENDED
PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

The Defendants, Galen D. Knight, Ph.D. and Terence J. Scallen, MD., Ph.D. hereby submit amended proposed Findings of Fact and Conclusions of Law for consideration by the Court in connection with the trial which commenced on June 25, 2001.

Findings of Fact

1. The Plaintiff University of New Mexico (hereinafter "UNM") is a body corporate established under the Constitution and Laws of the State of New Mexico (21-7-4, NMSA 1978).
2. Defendant Galen D. Knight, Ph.D. ("Knight") is a resident of the State of New Mexico, and Defendant Terence J. Scallen, MD., Ph.D. ("Scallen") is a resident of the State of California.
3. This matter was tried on the issues of a) whether or not new matter was added to the Vitaletheine Patents and Patent Applications in contravention of 35

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U.S.C. 132; b) ownership of the vitaletheine Patents and Patent Applications of Count I of the amended Complaint (*Doc.* 246); and c) Inventorship of the Vitaletheine Patents and Patent Applications (Count III) of the amended Complaint.

4. The Court has entered summary judgment in favor of the Plaintiff on Count II of the Complaint, holding that UNM is the owner of all right, title, and interest to the Beta-Alethine Patents and Applications (as defined in the Amended Complaint). The Court has also entered summary judgment on Count IV, holding that Knight and Scallen breached their contractual obligations with UNM by failing to execute assignments to the Vitaletheine Patents and Applications (as defined in the Amended Complaint). The Court has also entered summary judgment that the Defendants are the only joint, and properly named inventors of one of the Vitaletheine Issued Patents, U.S. Patent No. 5,370,868 (Count III).
5. The Court has dismissed Counts V, VI, and VII of the Amended Complaint.
6. Count III of the Amended Complaint arises under 35 U.S.C. 256 and 28 U.S.C. 2201.
7. The allegations of Counts I and III raise and allege issues that arise under the Patent Laws (35 U.S.C. 1 *et seq.*).
8. The patent application (Serial No. 08/317,548) that matured into United States Patent No. 5,578,313 (the “313 Patent”), entitled “Therapeutic Uses of Vitaletheine Modulators in Neoplasia”, was filed on October 4, 1994, as a divisional application of Application Serial No. 07/928,725, filed on August

- 12, 1992. The '313 Patent issued on November 26, 1996, with Knight and Scallen as listed inventors. Both Knight and Scallen signed a declaration of Inventorship that they were the joint inventors of the subject matter claimed in Application Serial No. 07/928,725.
9. The patent application (Serial No. 08/463,732) that matured into United States Patent No. 6,096,536 (the "536 Patent"), entitled "In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy Beta-Alanyl-Taurine", was filed on June 5, 1995, as a continuation application of a divisional application of United States Application Serial No. 07/941,926. The '536 Patent issued on August 1, 2000, with Knight and Scallen listed as inventors. Both Knight and Scallen signed a declaration of Inventorship that they were joint inventors of the subject matter claimed in Application Serial No. 07/941,926.
10. United States Patent Application Serial No. 08/463,784 (the "784 Application", now entitled "In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy Beta-Alanyl-Taurine", was filed on June 5, 1995, as a continuation application of a divisional application of Application Serial No. 07/941,926, with Knight and Scallen listed as inventors and is pending before the United States Patent and Trademark Office ("USPTO"). Both Knight and Scallen signed a declaration of Inventorship as to Application Serial No. 07/941,926.
11. United States Application Serial No. 08/466,143 (the "143 Application") entitled "Use of Vitaletheine Modulators in the Prophylaxis and Treatment of

Disease”, was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,893, with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of Inventorship as to United States Application No. 07/910,892.

12. United States Patent Application Serial No. 08/469,697 (the “697 Application”), entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Disease”, was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of inventorship as to United States Application No. 07/910,892.
13. United States Patent Application Serial No. 08/464,943 (the “943 Application”), entitled “Therapeutic Uses of Vitaletheine Modulators in Neoplasia”, was filed on June 5, 1995, as a divisional application of Application Serial No. 07/928,725, with Knight and Scallen listed as inventors, and is pending before the USPTO. Both Knight and Scallen signed a declaration of Inventorship that they were the joint inventors of the subject matter claimed in Application Serial No. 07/928,725.
14. In the ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, the ‘697 Application, and the ‘943 Application UNM made certain amendments to the molecular structure of certain compounds disclosed and claimed in the specifications thereof. These amendments were made subsequent to the filing of the application for each of the foregoing patents and applications. (The amendments made to the molecular structure of the

compounds in each application, are, with respect to the change of the chemical structure, each referred to as the "Amendment". The '313 Patent, the '536 Patent, the '784 Application, the '143 Application, the '697 Application, and the '943 Application are collectively, referred to herein as the "Patents and Applications".)

15. The Amendment to the Patents and Applications incorrectly deleted vitalethine from the claims.
16. The Amendment to the Patents and Applications relates to a compound correctly named in the Patents and Applications as filed as vitalethine V4. In the Amendment in each Patent and Application, the structure of vitalethine V4 was incorrectly changed to beta-alanyl-aurine (the "beta-alanyl-aurine Amendment").
17. The Amendment to the Patents and Applications also relates to a compound correctly named in the Patents and Applications as the "benzyl derivative of vitalethine". The Amendment in each Patent Application incorrectly changed the molecular structure for the benzyl derivative of vitalethine to carbobenzoxy beta-alanyl-aurine (the "carbobenzoxy beta-alanyl-aurine Amendment").
18. In the '313 Patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.

19. In the '536 Patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
20. In the '784 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
21. In the '143 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
22. In the '697 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
23. In the '943 Application, which has not yet issued as a patent, the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment were accepted by the USPTO in both the specification and the claims following an initial rejection based on new matter.
24. It was established at trial that the molecular structure disclosed in the beta-alanyl-aurine Amendment is not implicit in and is not an inherent

characteristic of the written disclosure and specification, as filed, of each of the Patents and Applications.

25. It was established at trial that the molecular structure disclosed in the carbobenzoxy beta-alanyl-taurine Amendment is not implicit in and is not an inherent characteristic of the written disclosure and specification, as filed, of each of the Patents and Applications.
26. The molecular structure disclosed in the beta-alanyl-taurine Amendment does not represent the true and correct compound resulting from the synthetic process for vitaletheine V4, disclosed in the Patents and Applications as filed.
27. The molecular structure disclosed in the carbobenzoxy beta-alanyl-taurine Amendment does not represent the true and correct compound resulting from the synthetic process for the benzyl derivative of vitaletheine disclosed in the Patents and Applications as filed.
28. In the '313 Patent, the '536 Patent, the '784 Application, the '143 Application, and '697 Application, protests were filed by defendant Galen Knight; the protests appear in the prosecution history file of each Patent and Application.
29. No amendment was made to the specification of the application maturing into U.S. Patent No. 5,370,868 that altered the molecular structure of any compound disclosed in the application as filed.
30. Hauser Chemical Research, Inc. ("Hauser") was retained by Dovetail Technologies, Inc. ("Dovetail"), the licensee of UNM, to synthesize certain compounds including vitaletheine, vitaletheine V4, and the benzyl derivative of vitaletheine. It was established at trial that Hauser's synthetic attempts (Dr.

Christopher Murray) differed significantly from the methods taught by Knight and Scallen in U.S. Patent 5,370,868 (the '868 Patent) and as also described in the Patents and Applications. The compounds obtained by Hauser, as a result of significant modifications of the Knight and Scallen synthetic methods were different than those disclosed by Knight and Scallen in the specifications and claims for the '868 Patent. Further, it was established at trial that the inability of Hauser to synthesize vitaethine was due to failure to follow precisely the synthetic methods described by Knight and Scallen in the '868 Patent.

31. Professional Analysis, Inc. ("PAI") was retained by UNM to synthesize vitaethine, the benzyl derivative of vitaetheine, and vitaetheine V4. It was shown at trial that the compounds obtained by PAI (Dr. Shield Wallace), as a result of significant modifications of the Knight and Scallen synthetic methods, were different than those disclosed by Knight and Scallen in the specifications and claims for the '868 Patent. Further, it was established at trial that the inability of Dr. Wallace to synthesize vitaethine was due to a failure to follow precisely the synthetic methods described by Knight and Scallen in the '868 Patent.
32. At trial the Defendants, Knight and Scallen, proved by a preponderance of the evidence that the methods described for the synthesis of vitaetheine V4, the benzyl derivative of vitaetheine, and vitaethine produce precisely these compounds as described in U.S. Patent 5,370,868. The Knight and Scallen methods of synthesis taught in the '868 Patent do not produce beta-alanyl-taurine or carbobenzoxy beta-alanyl-taurine.

33. Knight and Scallen presented convincing evidence at trial authenticating the existence, structure, and biological activity of vitaethine.
34. By a preponderance of the evidence, the facts at trial proved that the Examiners and USPTO were not correct in accepting the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine amendment and that such amendments, in fact, assigned a molecular structure that is not inherent in the compounds synthesized using the method described in the Patents and Applications.
35. No amendment was made as to the molecular structure of any compound included in U.S. Patent 5,370,868.
34. At trial UNM clearly averred that it does not believe in the existence of vitaethine or in the structures described in the '868 Patent for the other vitaethine modulators, i.e., the benzyl derivative of vitaethine and vitaethine V4 and therefore, the '868 Patent is subject to the requirements of the UNM 1983 Patent Policy, Section 5a, which states in pertinent part:

5a. ... "If the President decides that the University will not seek to exploit the invention or discovery for production of income the University shall promptly assign title thereto to the discoverer or inventor ...".

Conclusions of Law

1. The Court has personal jurisdiction over the parties.
2. Venue is properly laid in the District of New Mexico pursuant to 28 U.S.C. 1391(b).

3. The rights of the Defendants, Knight and Scallen, to relief necessarily depend on resolution of one or more substantive questions of United States Patent Law.
4. The relief sought by the Defendants, Knight and Scallen, in Count III pursuant to 35 U.S.C. 256 necessarily arises under United States Patent Law for which federal courts have exclusive jurisdiction.
5. This Court has subject matter jurisdiction over the claims now pending.
6. The last sentence of 35 U.S.C. 132 provides as follows: “No amendment shall introduce new matter into the disclosure of the invention.”
7. Determination of whether an amendment introduces new matter “depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter.” Brooktree Corporation v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1993).
8. If new matter is introduced during prosecution of a patent application, then claims depending on or incorporating such new matter are invalid under 35 U.S.C. 112, ¶ 1. Waldmar Link, GmbH & Co. v. Osteonics Corp., 32 F.3d 551, 558 (Fed. Cir. 1004); SDS USA, Inc. v. Ken Specialties, Inc., 122 F.Supp.2d 533, 544 (D.N.J. 2000).
9. A patent is presumed valid. 35 U.S.C. 282.
10. Therefore, U.S. Patent 5,370,868, issued on December 6, 1994 is presumed valid.
11. The Amendments do, as a matter of law, introduce new matter into the Patents and applications in contravention of 35 U.S.C. 132.

12. The Defendants Knight and Scallen are the properly named and sole inventors of the Patents and Applications as amended.
13. The Defendants, Knight and Scallen, are the only, joint and properly named inventors of the '313 Patent and the '536 Patent.
14. The Defendants, Knight and Scallen, are the only, joint and properly named inventors of the inventions disclosed in the '784 Application, the '143 Application, and the '697 Application, including without limitation the Amendments.
15. At trial UNM clearly averred that it does not believe in the existence of vitalethine or in the structures described in U.S. Patent 5,370,868 for the other vitaletheine modulators, i.e., the benzyl derivative of vitaletheine and vitaletheine V4. See Facts 32-34 above. Therefore, these compounds will not be "exploited for income" (UNM 1983 Patent Policy, Section 5a). Section 5a of the applicable UNM 1983 Patent Policy requires that UNM disclaim any ownership that it may have in U.S. Patent 5,370,868 and any other Patents or Applications which have not been amended to change the structures taught in the '868 Patent. Therefore, full right, title and interest in U.S. Patent 5,370,868 properly vests to the Inventors, Knight and Scallen. This ownership must be confirmed by a quitclaim assignment to Knight and Scallen from UNM.
16. The Defendants, Knight and Scallen, are the true and lawful owner of all right, title and interest to U.S. Patent 5,370,868, as to which no amendment to the structure of any compound therein was made, and all other patent applications

included within the Vitaletheine Patents and Applications as to which no amendment was made as to the structure of any compound included therein. See 18. below.

17. The Patents and Applications, including the '313 Patent, the '536 Patent, the '784 Application, the '143 Application, the '697 Application, and the '943 Application, are invalid as amended, due to the introduction of new matter in the Amendment (35 U.S.C. 132).

18. The Defendants, Knight and Scallen, are the true and lawful owners of all right, title and interest to the Patents and Applications, including the '313 Patent, the '536 Patent, the '784 Application, the '143 Application, the '697 Application, and the '943 Application, together with any patent or application, foreign or domestic, that is a continuation or divisional application of any of the foregoing, or which is a continuation or divisional application of a predecessor of any of the foregoing, in conformity with the UNM 1983 Patent Policy, section 5a, which states in pertinent part:

5a. ... "If the President decides that the University will not seek to exploit the invention or discovery for production of income the University shall promptly assign title thereto to the discoverer or inventor ...".

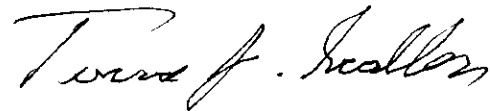
19. The Defendants, Knight and Scallen, are entitled to correction and reissue of the Patents and Applications, including the '313 Patent, the '536 Patent, the '784 Application, the '143 Application, the '697 Application, and the '943 Application, together with any patent or application, foreign or domestic, that is a continuation or divisional application of any of the foregoing, or which is

a continuation or divisional application of a predecessor of any of the foregoing, which were erroneously amended by the insertion of new matter.

For the reasons of Fact and Law set forth herein Knight and Scallen Pray the Court to grant judgment in the Defendants' favor and to sign the attached Order.

Dated this 2nd day of July, 2001.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Terence J. Scallen".

Terence J. Scallen, MD., Ph.D.
Defendant, *Pro Se*

A handwritten signature in cursive script, appearing to read "Galen D. Knight".

Galen D. Knight, Ph.D.
Defendant, *Pro Se*

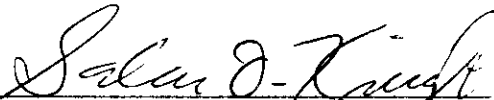
CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing pleading and attached was sent via first class mail this 2nd day of July, 2001 to the following:

Paul Adams
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Terence J. Scallen


Galen D. Knight

**THE EXHIBITS ATTACHED TO THIS
PLEADING ARE TOO VOLUMINOUS TO
SCAN. SAID EXHIBITS ARE ATTACHED
TO THE ORIGINAL PLEADING IN THE
CASE FILE WHICH IS LOCATED IN THE
RECORDS DEPARTMENT U. S. DISTRICT
COURT CLERK'S OFFICE.**